UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION and NORTH AMERICAN CUSTOM LABORATORIES, LLC d/b/a FARMAKEIO CUSTOM COMPOUNDING, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION and DR. MARTIN A. MAKARY, Defendants, and ELI LILLY AND COMPANY, Intervenor-Defendant.	Case No. 4:24-cv-953-P

ELI LILLY AND COMPANY'S MEMORANDUM OF LAW
IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

After spending years developing and securing approval from the U.S. Food and Drug Administration ("FDA") to sell its groundbreaking tirzepatide medicines, Eli Lilly and Company ("Lilly") committed tens of billions of dollars to ensuring that its supply will continue to satisfy unprecedented patient demand. Those efforts have paid off: All doses of Lilly's tirzepatide medicines have been available since at least August 2024. That is not just by Lilly's telling. After carefully examining comprehensive national data showing that supply not only exceeded current demand but would continue to satisfy projected demand, FDA deemed the shortage resolved in a December 2024 Decision Memorandum. Before it did so, moreover, FDA considered all the submissions Plaintiffs and their allies could muster in support of a continued finding of shortage. But in the end, Plaintiffs' data simply consisted of cherry-picked, unreliable snapshots, many of which were missing basic information and some of which affirmatively undermined their claims.

Plaintiffs are now on their fourth attempt (including the "quasi-brief" they submitted after asking for judgment to be entered against them, *see* ECF No. 120, at 3) to convince this Court that FDA violated the Administrative Procedure Act ("APA") when it determined that the tirzepatide shortage was resolved by December 19, 2024, at the latest. The fourth time is not the charm. This Court already concluded that FDA's reasoning and the data cited in its Decision Memorandum fully supported its determination. Now the full administrative record makes that conclusion clear beyond cavil. Plaintiffs' procedural objections are just legal arguments that this Court has already correctly rejected and the Fifth Circuit recently found wanting. And while Plaintiffs dress up some of their arbitrary-and-capricious arguments in new garb, they cannot overcome the basic flaws with their position, which likely explains why the Fifth Circuit swiftly brushed their arguments aside. FDA scrutinized the comprehensive, quantitative data Lilly submitted, and it reasonably found those detailed submissions to be (far) more reliable and probative than Plaintiffs' and their

allies' scattershot submissions. No matter how many ways Plaintiffs try to deny it, FDA's consideration of the evidence easily satisfies the arbitrary-and-capricious standard. Finally, Plaintiffs' contrary-to-law claim is equally doomed. While Plaintiffs articulate some new theories in support of their claim that FDA's interpretation and application of the Federal Food, Drug, and Cosmetic Act ("FDCA") was incorrect, Plaintiffs' (mis)construction of the statute not only defies text, context, and common sense but yields confounding results. This Court should deny Plaintiffs' motion on all counts, and instead grant summary judgment for Defendants.

ARGUMENT

"When assessing a summary judgment motion in an APA case, 'the district judge sits as an appellate tribunal.'" *Permian Basin Petroleum Ass'n v. Dep't of the Interior*, 127 F.Supp.3d 700, 706 (W.D. Tex. 2015) (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)). Judicial review under the APA is limited to the administrative record, 5 U.S.C. §706, and "the party challenging an agency's action as arbitrary and capricious bears the burden of proof," *San Luis Obispo Mothers for Peace v. NRC*, 789 F.2d 26, 37 (D.C. Cir. 1986).

In this case, none of Plaintiffs' claims are persuasive, much less correct as a matter of law, so their summary judgment motion should be denied. Plaintiffs' procedural claims (Counts One and Six) fail for two independent reasons. First, as this Court already concluded, FDA's decision was an adjudication exempt from notice-and-comment requirements and publication in the Federal Register. Second, even if certain procedures were required, Plaintiffs received all the notice and opportunity to comment that the APA would have afforded them. Plaintiffs' arbitrary-and-capricious claims (Counts Two, Three, and Four) also fail. FDA acted reasonably in selecting the appropriate time period for consideration of whether the shortage had abated, and it reasonably evaluated both Lilly's comprehensive submissions and the scattershot submissions from Plaintiffs and their allies. Plaintiffs now argue that FDA outsourced decision-making responsibility, failed

to consider alternatives, and did not properly explain its supply-and-demand findings. But their new theories are no more persuasive than their original ones and, if anything, are even more squarely belied by the record. Finally, Plaintiffs' "contrary to law" claim (Count Five) advances an interpretation of the statute that defies text, ignores context, and leads to genuine absurdity in multiple ways.

I. Plaintiffs' Procedural Claims Fail.

A. Plaintiffs make only minor adjustments to their original procedural objections, which this Court already rejected at the preliminary-injunction stage. *See* ECF No. 100, at 6-17. Plaintiffs (again) contend that "FDA's failure to follow the APA's notice-and-comment procedures [was] unlawful" because they believe FDA's decision was a rule. Plfts.SJ.Mem.27. And they (again) argue that FDA erred by not publishing its decision in the Federal Register. *Id.* at 33. As Lilly explained in its summary judgment brief, *see* Lilly.SJ.Mem.21-25, and for the same reasons this Court laid out in "its thorough opinion explaining its denial of a preliminary injunction," CA5.Dkt.98-1 at 3, these arguments all fail. FDA's decision was a textbook informal adjudication for which formal notice and comment was neither required nor appropriate. Plaintiffs' contrary argument continues to confuse what constitutes a rule with what renders a rule legislative rather than interpretive. Because FDA's decision was not a rule at all, it makes no difference that it, like many adjudications, has the force and effect of law, affects multiple entities, and applies prospectively.

B. Plaintiffs' handful of new arguments do not undermine that conclusion.

1. Plaintiffs assert that FDA's determination that the shortage of Lilly's tirzepatide products had resolved must be a rule because *other* courts considering *other* listing decisions based on *other* statutes have held that those *other* decisions required formal rulemaking. Pltfs.SJ.Mem.28 (collecting cases). But the cases they cite all involved different laws and different facts. *Cf.*

Twitter, Inc. v. Taamneh, 598 U.S. 471, 507 (2023) (Jackson, J., concurring) ("[Different] cases presenting different allegations and different records may lead to different conclusions."). In five of their six cases, the relevant statute explicitly required the agency to act through rulemaking. *See Green Rock LLC v. IRS*, 104 F.4th 220 (11th Cir. 2024); *Mann Constr., Inc. v. United States*, 27 F.4th 1138, 1143 (6th Cir. 2022); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1401-04 (9th Cir. 1995); *Ctr. for Bio. Diversity v. U.S. Fish and Wildlife Serv.*, 698 F.Supp.3d 39 (D.D.C. 2023); *Ctr. for Bio. Diversity v. Everson*, 435 F.Supp.3d 69 (D.D.C. 2020). Congress used similar mandatory language in *other* parts of the FDCA, *e.g.*, 21 U.S.C. §353b(a)(2)(A)(i)(I)-(III), but it conspicuously chose not to do so when it came to shortage determinations—likely because it would make no sense to force FDA to go through formal notice-and-comment procedures that will often take longer than a drug shortage to resolve and be incompatible with the statute's confidentiality provisions for business information. *See* ECF No. 100, at 8-9 (holding that notice-and-comment rulemaking "is incompatible with Congress's mandate to keep an up-to-date list").[1]

As for Plaintiffs' sixth case, *Anne Arundel County v. EPA*, 963 F.2d 412 (D.C. Cir. 1992), the agency action there was placing a new site "on the National Priorities List," also known as the Superfund list, *id.* at 413. Whether to add a new site to the Superfund list entails a complex policy judgment made "on the basis of the Hazard Ranking System[,] … a set of criteria which measure the risk of harm to the environment from the migrations of hazardous substances from the site by way of three routes: groundwater, surface water, and/or air." *Id.* at 414. That type of risk-assessing policy judgment is worlds away from this context, where FDA's determination of

[1] Contrast that with the two most prominent statutory "lists" in the biopharmaceutical space—the Orange Book and the Purple Book, respectively—for which the relevant statutory language is similar to §356e(a). *See* 21 U.S.C. §355(j)(7) ("the Secretary shall publish and make available to the public …"); 42 U.S.C. §262(k)(9)(A)(i) ("the Secretary shall publish and make available to the public in a searchable, electronic format …"). Being added to either Book list has clear legal consequences for the entire healthcare delivery system. And being added to either has prospective effect. Yet neither list has ever been promulgated or amended through notice and comment.

whether a shortage exists entails looking at supply and demand in real time, *see* Lilly.SJ.Mem.22—something that a protracted notice-and-comment proceeding would frustrate rather than facilitate. *See* ECF No. 100, at 10-11 (illustrating that problem). Furthermore, whereas FDA will (and is required to) remove a drug from the shortage list as soon as demand no longer exceeds supply, it usually takes years and millions (if not billions) of dollars to clean up a Superfund site and have it *removed* from the National Priorities List, which is why property owners are entitled to the most fulsome administrative process before a site is *added* to the list. Here, by contrast, FDA does not use notice and comment before adding a drug to the shortage list—which, as this Court correctly recognized, makes this "a 'lose-lose scenario'" for Plaintiffs. *Id.* at 11; *see also* Lilly.SJ.Mem.21.

Plaintiffs next argue that FDA's decision cannot have been the product of an adjudication because there were no named parties. Pltfs.SJ.Mem.29. That is both wrong and irrelevant. While FDA's order might not explicitly name a party, the title of the Declaratory Order names the medicines at issue: "Tirzepatide Injection Products (Mounjaro and Zepbound)." Lilly App. 1 (FDA_000001).[2] That obviously makes Lilly a party to the decision as the manufacturer of the medicines, just as an "*In re*" title would; after all, the shortage list entry for Lilly's products was statutorily required to include "[t]he name of the drug in shortage," 21 U.S.C. §356e(b)(1), as well as "[t]he name of each manufacturer of such drug." *Id.* §356e(b)(2). In any event, the way FDA captioned its decision makes no difference. "[A]n agency need not be presented with a specific dispute between two parties in order to use [5 U.S.C.] §554(e)'s declaratory ruling mechanism.'" *City of Arlington v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012) (quoting 5 U.S.C. §554(e)). Agencies can also use adjudications to resolve disputes that will "have an immediate and determinable

[2] Citations to "Lilly App." are to the separate appendix Lilly filed with its motion for summary judgment. *See* ECF No. 128.

impact on specific factual scenarios." *Id.* FDA's decision did just that in declaring the shortage of a specific and explicitly identified set of medicines resolved. *See* Lilly.SJ.Mem.22 (explaining that FDA's determination immediately prohibited outsourcing facilities from compounding tirzepatide). In short, FDA's decision was a standard informal adjudication for which neither full notice-and-comment treatment nor publication in the Federal Register was required. *See* ECF No. 100, at 6 (noting that Plaintiffs' notice-and-comment argument and Federal Register argument "are both predicated on the Delisting Action being a rule"); Lilly.SJ.Mem.24-25.

2. Plaintiffs' procedural claims fail for the independent reason that Plaintiffs received all the benefits of a rulemaking (and then some). *See* Lilly.SJ.Mem.25-27. Despite the plain language of 5 U.S.C. §706 and binding Supreme Court precedent, Plaintiffs boldly proclaim that prejudice does not matter. Pltfs.SJ.Mem.32. But the sole case they cite in support of that claim, *W & T Offshore, Inc. v. Bernhardt*, 946 F.3d 227 (5th Cir. 2019), did not discuss *either* §706 *or* harmless error. That is unsurprising, as cases from this Circuit and others make clear that §706 says what it means and means what it says: Agency action that does not prejudice the complaining party need not be set aside. *See City of Arlington*, 668 F.3d at 243-46; Lilly.SJ.Mem.25 (citing cases). As for Plaintiffs' half-hearted assertion that "FDA's failure prejudiced [them]," the less said the better. Pltfs.SJ.Mem.32. Plaintiffs cannot help but admit that they "were aware of FDA's consideration." *Id.* And they were not alone: Plaintiffs undertook an extensive "internet letter-writing campaign," Lilly App. 31 (FDA_000031), to ensure that their supporters would submit their views to FDA in force, which they did. Their submissions failed to persuade not because of any infirmities with FDA's process but because they were unpersuasive.

II. Plaintiffs' Arbitrary-And-Capricious Claims Fail.

Plaintiffs' substantive arguments are equally meritless. Plaintiffs contend that FDA "fail[ed] to provide a satisfactory explanation of the grounds of its decision" (Count Two),

Pltfs.SJ.Mem.8-15, and that FDA's review of Lilly's data (Count Three) and its treatment of Plaintiffs' and their allies' scattershot submissions (Count Four) are not supported by "substantial evidence," *id.* at 17-27. Whether considered together or in isolation, each claim fails.

As Lilly explained at length in its own summary judgment brief, FDA's delisting decision was reasonable and rationally connected to the facts. Lilly.SJ.Mem.27-38. Contrary to Plaintiffs' assertions, FDA properly explained its decision. And FDA's consideration of the evidence before it was reasonable. FDA carefully assessed quantitative data Lilly provided [redacted], which demonstrated that Lilly's supply was meeting and exceeding nationwide demand at the time of the decision (and for months before then) and would continue to do so moving forward. *See id.* at 28-34 (citing record). Plaintiffs' efforts to pick holes in that evidence reflect confusion on their part, not FDA's. Finally, FDA reasonably found that the scattershot anecdotes submitted by Plaintiffs and other interested parties did not undermine, and in many instances were consistent with, Lilly's detailed evidentiary submissions. *See id.* at 34-38. FDA plainly acted reasonably in laying out the parameters of its decision and assessing the evidence before it. Indeed, on this record, FDA could not have reasonably found anything other than that the shortage was over. Plaintiffs' arbitrary-and-capricious claims fail as a matter of law. This Court should deny Plaintiffs' summary judgment on their Second, Third, and Fourth Counts, and instead grant summary judgment to Defendants.

A. FDA properly identified key parameters and explained its decision.

Plaintiffs first claim that FDA failed to "provide a satisfactory explanation of the grounds of its decision" on various fronts. Pltfs.SJ.Mem.8. Specifically, they argue that FDA improperly "[o]utsourced" its decision-making responsibility to Lilly, failed to explain its choice of time period, did not consider supposedly obvious alternatives, and failed to explain its findings

regarding supply or demand. *Id.* at 9-15. Some of these arguments are self-defeating. All are meritless.

1. Plaintiffs begin by arguing, for the first time in this case, that FDA "[o]utsourced" its shortage decision to Lilly. *Id.* at 9. There is a reason they have waited until their fourth try to raise this argument: It is demonstrably false. Lilly did not decide that its medicines are no longer in shortage. FDA did. And FDA did not give Lilly deference—"quasi" or otherwise—in making that decision. To the contrary, as part of its ongoing review, FDA repeatedly asked Lilly for clarifications or additional data to help the agency answer the ultimate question of whether any shortage has ended. For example, in an [redacted] email, FDA asked [redacted] in data charts that Lilly had been providing. Lilly App. 77 (FDA_000415). Lilly responded to that inquiry by explaining to FDA in a [redacted] letter how it determined [redacted]." *Id.* at 85-86 (FDA_000427-000428). And in a [redacted] email, FDA asked Lilly to explain [redacted]. *Id.* at 111 (FDA_000456). Lilly answered that question (among others) in a [redacted] letter, explaining that [redacted]. *Id.* at 131-32 (FDA_000476-000477). To be sure, FDA ultimately concluded that the data did support that the shortage has ended—a conclusion with which Lilly agrees. *See, e.g.*, *id.* at 18, 20, 24, 27 (FDA_000018, 020, 024, 027). But that in no way indicates that FDA let Lilly determine any of the key parameters of the decision, let alone that "all relevant decisions were made by the manufacturer,"

Pltfs.SJ.Mem.8-9. It just shows that Lilly's detailed submissions proved beyond doubt that any shortage was over.

2. Plaintiffs next return to their argument that FDA did not properly explain what time period it was analyzing. *Id.* at 10. That argument fares no better now than before. As this Court previously put it, "the FDA sufficiently identified what time period it considered in making the shortage determination." ECF No. 100, at 18; *see* Lilly App. 13, 19-22, 26-27 (FDA_000013, 019-22, 026-27); *see also* Lilly.MSJ.Mem.27-28. FDA looked at evidence [redacted] to determine whether Lilly's supply was presently meeting demand and would continue to do so [redacted]—and it has been.

Plaintiffs continue to assert that FDA considered and presented data using different time frames, which Plaintiffs say "do not permit anyone to infer *post hoc* what time period the agency decided to review." Pltfs.SJ.Mem.10. That argument is in serious tension with the sentence that precedes it, in which Plaintiffs seem to have had no trouble discerning that FDA considered data over a "[redacted]." *Id.* It also is tough to square with Plaintiffs' contrary-to-law argument, which is premised on the notion that FDA chose that [redacted]. *See id.* at 15; *infra* pp.23-28. In all events, Plaintiffs' argument misses the mark. What they are really complaining about is the fact that FDA considered different types of data from different time frames *within* those [redacted] to zoom in and out and to get a holistic picture. But that in no way obscures the fact that FDA made its shortage assessment based on data [redacted], as Plaintiffs themselves clearly understand. Nor does it provide any basis to second-guess FDA's decision, as nothing in law or logic confines an agency to considering only a single type of data across a particular time frame. To the contrary, an agency acts eminently reasonably (and certainly not arbitrarily and capriciously) when it considers different types of available data

from different angles in making the kind of present-day and predictive assessment at issue here, as that is the best way to cross-check results. *See infra* pp.14-18.

3. Plaintiffs fare no better in arguing that FDA failed to address obvious alternatives in selecting the time period to assess. *See* Pltfs.SJ.Mem.11-13. FDA did not need to explain why it did not use Plaintiffs' proposed alternatives because those purportedly "obvious candidates" are not alternatives in the relevant sense—as Plaintiffs' efforts to argue otherwise make clear. *Id.*

Plaintiffs invoke *State Farm*, where the Court faulted the Secretary of Transportation for rescinding a requirement that automobiles include both automatic seatbelts and airbags without considering the alternative of "an airbags-only" requirement, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983), and *Regents*, where Homeland Security rescinded a policy that extended enforcement discretion and benefits to unlawfully present persons without considering the alternative of rescinding only the illegal benefits aspect while leaving the enforcement discretion policy in place, *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 591 U.S. 1, 27-30 (2020). *See* Pltfs.SJ.Mem.11-12. In both of those cases, the problem was that the agency failed to consider a *different*, more narrowly tailored agency action. Here, by contrast, FDA was not enacting policy; it was answering a factual question: whether demand exceeded supply for Lilly's medicines. Plaintiffs' argument is not that FDA should have considered some alternative action to taking Lilly's medicines off the shortage list (not that that there was any evident alternative).[3] They simply think that FDA should have focused on a narrower data set when deciding whether to do so—a proposition for which Plaintiffs cite precisely nothing, because there is nothing in law or logic that supports it.

[3] Indeed, Plaintiffs themselves cannot seem to decide what they think the "right" time period would be. They say five years is too long, Pltfs.SJ.Mem.10, and one month is too short, Pltfs.SJ.Mem.21, but it is anyone's guess where between those poles Plaintiffs think the goldilocks zone lies. That reflects a basic reality inherent in arbitrary-and-capricious review, which is that there often is no singular ideal framework within which an agency must operate.

At any rate, Plaintiffs' argument fails on its own terms. Plaintiffs continue to fixate on the notion of a "month-to-month" supply-and-demand analysis. *Id.* at 12-13. But if FDA assessed data on a monthly (or even daily) basis, it still would have needed to account for whatever surplus Lilly carried into that month (or day) to properly determine if supply was meeting demand. As this Court thus already recognized, a month-to-month analysis would help Plaintiffs only if FDA ignored the reality that "surplus carries over," which it could not coherently do. ECF No. 100, at 23. Indeed, *that* would have been arbitrary and capricious. *See* Lilly.SJ.Mem.33 (explaining that "Lilly's supply of its medicines does not reset to zero at the start of each month," but rather "excess supply in one month carries over to the next month"). Because cumulative data cannot reasonably be ignored in a supply and demand analysis, a proper consideration under *any* time frame would have led to the same conclusion: Lilly's supply of Mounjaro® and Zepbound® is meeting or exceeding demand and will continue to do so going forward.

For similar reasons, Plaintiffs' contention that FDA needed to explain its [redacted], Pltfs.SJ.Mem.13, is without merit. As this Court has already explained, "a period of time requires a starting and ending point," which made it reasonable for FDA to [redacted]. ECF No. 100, at 23. And [redacted] would have made no sense because, as part of the relevant time period considered, FDA needed to account for accumulated supply [redacted].

4. Finally, Plaintiffs' argument that FDA failed to sufficiently explain its supply and demand choices reflects a basic misunderstanding (or mischaracterization) of how FDA evaluated the relevant data. *See* Pltfs.SJ.Mem.13-15. Plaintiffs characterize FDA's various presentations of supply and demand data as "competing showings … present[ing] competing views." *Id.* at 13. The most charitable description of this argument is that it misses the forest for the trees. To be

sure, FDA's tables in its decision memorandum present data in different formats: Table 1 shows net inventory balances at [redacted] intervals from [redacted] (Lilly App. 19 (FDA_000019)); Tables 2-4 depict historical cumulative supply and demand data from [redacted] (*id.* at 20-22 (FDA_000020-000022)); Table 5 highlights Lilly's shipping numbers in [redacted] as well as wholesalers' average daily inventory during those months (*id.* at 24 (FDA_000024)); and Table 6 gives projected cumulative supply and demand data [redacted] (*id.* at 27 (FDA_000027)). But those tables do not reflect "competing" data or considerations. They are just different ways of coming at the same basic question: Is Lilly's supply meeting demand? And all of them point to the same answer: Yes.[4]

Plaintiffs' efforts to identify discrepancies among those tables suffer from the same problem: They obscure the reality (explained by FDA) that the tables represent *different things* that are all relevant to question before FDA—which is what one would expect (or at least hope for) in a robust analysis. For example, Plaintiffs note that Table 1 shows available inventory on [redacted] of around [redacted] doses and ask how this can be squared with Table 4, which shows cumulative supply exceeding demand at [redacted] by a higher number. *Id.* at 19, 22 (FDA_000019, 022). But FDA asked Lilly the same question, and Lilly responded by explaining that [redacted] *Id.* at 132

[4] Indeed, had FDA *not* investigated the issue from multiple angles, Plaintiffs and their allies almost certainly would have complained that it did not do enough. That FDA performed a robust analysis is a reason for credit, not criticism.

(FDA_000477). In other words, when Lilly reported the net inventory as of a particular day near the end of a month, that number would not—and could not—represent the net of total supply and demand for that month. Plaintiffs simply misunderstand (or misrepresent) what the data show. In stark contrast, FDA's explanation of what each table represents confirms that it well understood that the stock reports and cumulative data tables provide different pieces of the puzzle. *See, e.g.*, *id.* at 17 (FDA_000017) (explaining stock reports); *id.* at 19 (FDA_000019) (explaining cumulative data).

Indeed, Plaintiffs acknowledge as much, Pltfs.SJ.Mem.14 (quoting FDA_000477); they just purport not to understand why FDA would rely on the cumulative data at all if it were not meant to represent a net inventory balance. *See id.* But FDA made perfectly clear why it still considered that data valuable: It "[redacted]." Lilly App. at 19 (FDA_000019). Particularly when buttressed by the more specific stock reports (which capture a snapshot in time), the tables (which provide relevant information about inventory trends) thus collectively demonstrate both that Lilly was fulfilling wholesaler orders while maintaining excess inventory and that Lilly had built up a sufficient reserve of supply throughout the year to continue to meet demand moving forward—just as FDA (correctly) concluded.

In a last grab, Plaintiffs argue that FDA "failed to consider obvious questions about product storage, loss, and longevity" that they say should have factored into its analysis. Pltfs.SJ.Mem.14. But, again, calling something "obvious" does not make it so. And they offer only rank speculation that Lilly was treating as inventory medicines that are no longer viable or routinely distributing newer medicines while leaving older ones on the shelf. Indeed, the sole piece of "evidence" they supply to question how long Lilly's medicines are viable is a screenshot indicating availability of

"[redacted]." Pltfs.SJ.Mem.15 (citing FDA_001451). It is not even clear whether that language has anything to do with expiration dates. *See infra* p.20 & note 8. In all events, Plaintiffs' evidence-free speculation provides no basis whatsoever to suggest that FDA was counting as part of Lilly's inventory medicines that are no longer viable.

* * *

At bottom, FDA sufficiently identified its relevant time period; Plaintiffs' "obvious" alternatives are not "obvious" or alternatives at all; and FDA explained its findings of supply and demand vis-à-vis Lilly's submissions. Because FDA's "path may reasonably be discerned," *Tex. Med. Ass'n v. HHS*, 120 F.4th 494, 504 (5th Cir. 2024), the Court should deny Plaintiffs' motion as to Count Two, and instead grant summary judgment for Defendants.

B. FDA's analysis of and reliance on Lilly's comprehensive data was reasonable and reasonably explained.

Plaintiffs next argue that FDA's findings regarding Lilly's data are arbitrary and capricious because they are not supported by substantial evidence. Pltfs.SJ.Mem.17-23. But Plaintiffs' various attacks on Lilly's data and FDA's analysis of that data get them nowhere. As this Court explained at the preliminary-injunction stage, the pertinent question "is whether the FDA's decision, that supply of the Lilly drugs outpaced demand for a period of time, was reasonable in light of the evidence before it." ECF No. 100, at 21. The answer easily remains "affirmative." *Id.*

1. Lilly's opening brief explained in detail the evidence that it submitted for FDA's consideration on the shortage question. *See* Lilly.SJ.Mem.29-34. Those submissions included [redacted] stock reports showing that Lilly was fulfilling all existing wholesaler orders while maintaining anywhere from [redacted] doses of finished product and [redacted] doses of semi-finished product in its net inventory from [redacted]. *Id.* at 29.

Lilly also provided "historic[al] data on monthly cumulative supply and demand" starting in [redacted], which allowed FDA to see that Lilly had built an excess of supply [redacted], to the point where it had more than [redacted] excess doses by the end of [redacted] (not including the [redacted] units in inventory) that it could use in future months to help meet demand or continue to build excess supply. *Id.* at 30 (referencing Lilly App. 19-22 (FDA_000019-000022)). Lilly forecasted supply and demand [redacted], showing that its supply would continue to meet demand going forward. *Id.* at 31-32.[5] And Lilly provided data about inventory in the distribution channel, including wholesaler inventory. *Id.* at 32. FDA probed this data, *contra* Pltfs.SJ.Mem.18 (suggesting FDA "blindly accept[ed]" Lilly's submission), and asked Lilly follow-up questions to help it analyze Lilly's submissions, Lilly App. 77-79, 108-11 (FDA_000415-000417, 000453-000456), and Lilly responded with detailed answers, *see, e.g.*, *id.* at 80-90, 114-32, 143-47 (FDA_000422-000432, 000459-000477, 000488-000492). Considering and presenting data in these various formats and time frames was reasonable because they gave FDA a holistic picture of the supply-and-demand situation. And the conclusion FDA drew from this data—that Lilly's "supply is currently meeting or exceeding demand and … will meet or exceed projected demand across all [dosage] strengths," *id.* at 27 (FDA_000027)—is plainly supported by all of that substantial evidence.

2. As they did at the preliminary-injunction stage, *see id.* at 26-30 (FDA_000026-000030),

[5] Lilly recently learned that FDA incorrectly tabulated one row in Table 6 of its December 19 decision memorandum, which led Lilly to use slightly (but immaterially) incorrect figures in its own summary judgment brief. *See* Lilly App. 27, tbl. 6 (FDA_000027); Lilly.SJ.Mem.31. Both filings indicate that Lilly had a cumulative supply of approximately [redacted] The correct totals for cumulative supply in those months—which are reflected in the table FDA put together, but for reasons unknown were incorrectly summed—are approximately [redacted]. Again, FDA's table and Lilly's reporting of its net surplus were based on the correct supply numbers, and they continue to reflect that Lilly maintained surplus supply between approximately [redacted] throughout those months. Lilly App. 27, tbl. 6 (FDA_000027); Lilly.SJ.Mem.31.

Plaintiffs contend that FDA's conclusion that the shortage had resolved was arbitrary and capricious because FDA considered data from different time frames. Pltfs.SJ.Mem.18. But as already explained, FDA's decision to do so was eminently reasonable, as that enabled FDA to both zoom in and zoom out perspectives, giving it a holistic view of the situation. *See supra* p.9. Indeed, it would have bordered on arbitrary and capricious to *ignore* relevant data just because it analyzed the question through a slightly different lens. Plaintiffs again suggest that FDA should have confined its consideration of supply and demand to monthly figures and disregarded any cumulative tabulations. Pltfs.SJ.Mem.18-20. But their fuzzy math continues to obscure, rather than clarify, the true state of supply and demand. *See* Lilly.SJ.Mem.33-34 (explaining why supply must be assessed on a cumulative basis).

Indeed, Plaintiffs are more than happy to present a cumulative assessment of *demand*, *see* Pltfs.SJ.Mem.19, tbl. B, which they try to utilize to claim a shortage "to the tune of [redacted]," *id.* at 19. But the only thing worse than ignoring cumulative figures entirely is considering cumulative demand while ignoring cumulative supply, as it is incoherent to ask whether demand is being met without counting all available supply. In point of fact, Plaintiffs can suggest [redacted], *see id.* at 19, tbl. C, only by ignoring the fact that [redacted], without even considering accumulated surplus from prior months. The same error infects Plaintiffs' claims [redacted] Once one appreciates that assessing whether a shortage exists at any given moment depends in part on the status of supply and demand *leading up to that moment* (i.e., historical cumulative data), *see infra* pp.27-29, it becomes clear that FDA *had* to consider Lilly's historical cumulative data. After all, it would be the height of arbitrary and capriciousness to claim a shortage by looking at all demand while ignoring substantial supply. Indeed, even Plaintiffs

acknowledge that "supply and demand must be viewed *together* across a consistent time period." Pltfs.SJ.Mem.20.

Plaintiffs next make much of the fact that FDA found that Lilly "is 'now able to supply over [redacted] doses [of tirzepatide injection products] per month.'" Pltfs.SJ.Mem.20 (quoting Lilly App. 25 (FDA_000025)). But this was a statement about Lilly's *capacity*, not its historical output. That Lilly has not historically manufactured [redacted] doses in a month in no way undermines a finding that it is now capable of doing so. After all, part of the reason Lilly is now able to meet all demand is because it has invested heavily in increasing its manufacturing capacity. And as Plaintiffs admit, Lilly was within striking distance of [redacted] doses in earlier months in [redacted]. *See* Pltfs.SJ.Mem.19-20.[6]

Finally, Plaintiffs try to compare two different data points [redacted] to demonstrate a shortage during those two months. *Id.* at 21-22. Plaintiffs start by pointing to Table 5 in FDA's decision memo, which shows that Lilly shipped [redacted]. *Id.* at 22; *see also* Lilly App. 24, tbl. 5 (FDA_000024). They then highlight that demand for that [redacted] was [redacted]. Pltfs.SJ.Mem.22; *see also* Lilly App. 22, tbl. 4 (FDA_000022). Compare these two numbers, Plaintiffs say, and voilà! [redacted]. But, as with so many of their contentions, Plaintiffs miss the important details.

For one thing, Table 5 represents only what Lilly [redacted]; it does not account for any excess doses that Lilly had on hand at the beginning of those months,

[6] Plaintiffs in one breath criticize FDA for looking at too broad a period, and then base a critique on the time period under review being too small—even though the one month at issue was the most recent month (and thus the most "up-to-date" possible).

which is part of the calculation for Lilly's total supply. For another thing, Table 5 represents what Lilly [redacted]. That is important, because while Lilly might have received an order from a wholesaler at the [redacted] (which would be reflected in Table 4's tabulations of demand), it might not have [redacted] (in which case it would not be reflected in Table 5). And Lilly regularly ships quantities [redacted]. Pltfs.SJ.Mem.22; *see also* Lilly.SJ.Mem.30 (discussing [redacted] being shipped [redacted]); Lilly App. 94 (FDA_000436) (discussing planned replenishment shipment of [redacted]). [redacted]. *Id.* at 131 (FDA_000476) (emphasis added). Plaintiffs' supposed deficit is thus easily explainable when one understands what each piece of data reflects. In fact, Table 4 shows that total supply for [redacted], which suffices to refute any claim that there was a deficit in those months. *Id.* at 22 (FDA_000022). Plaintiffs provide no reason to think that FDA did not understand all of that when it made its decision.

C. FDA properly rejected Plaintiffs' unreliable, poor-quality information.

Plaintiffs' final APA arguments are a rehash of arguments this Court already rejected—that FDA improperly dismissed substantial evidence of ongoing shortage. Pltfs.SJ.Mem.23-27. Plaintiffs even go so far as to accuse FDA of having "treated conflicting evidence … with an almost breathtaking lack of evenhandedness." *Id.* at 23 (quoting *Sutter E. Bay Hosps. v. NLRB*, 687 F.3d 424, 437 (D.C. Cir. 2012)). This argument runs aground on the rocks of reality, as Plaintiffs can make such a bold accusation only by ignoring or mischaracterizing FDA's decision.

In reality, FDA spent 13 of the 32 pages of its decision memorandum addressing the various categories of information Plaintiffs and their allies submitted purporting to show shortage, and it explained—in detail—exactly why it did not find the information probative. *See* Lilly App. 28-41 (FDA_000028-000041). Nothing in Plaintiffs' summary judgment brief undermines that conclusion in the slightest.

1. Plaintiffs start by pointing to screenshots that they say show that wholesalers had no supply or restricted supply of Lilly's tirzepatide products. Pltfs.SJ.Mem.23-24. FDA assessed these screenshots and explained that they suffered from myriad limitations, including that many were undated, did not account for distribution chain dynamics unrelated to the adequacy of supply, and "show[ed] at most only disconnected individual 'snapshots' in time." Lilly App. 31-33 (FDA_000031-000033). In light of those limitations, FDA reasonably concluded that "[t]he evidence provided by Lilly … provide[d] a much fuller picture of the supply and demand situation both over time, and at the national level." *Id.* at 33 (FDA_000033).

Plaintiffs resist that conclusion, pointing to some submissions that were dated or were accompanied by cover notes that provided dates. Pltfs.SJ.Mem.24 (citing Pltfs. App. 218-34 (FDA_000677-000693); *id.* at 387-88 (FDA_000846-00047); *id.* at 395-97 (FDA_000854-000856); *id.* at 402-03 (FDA_000861-000862)).[7] But this cherry-picked selection ignores the high volume of screenshots that had no date information at all. *See, e.g.*, Pltfs. App. 523-557 (FDA_000982-001016); *id.* at 568-631 (FDA_001430-0001493). Moreover, although some of the cover notes have dates, there is no way to verify that the screenshots submitted with those notes are actually from that date. For instance, FDA_001493 (Pltfs. App. 631) is a screenshot dated

[7] It is unclear why Plaintiffs cite Pltfs. App. 402-03 (FDA_000861-000862), as those pages are a cover note for a comment on FDA's compounding docket from Birchwood Family Medicine LLC.

November 21, 2024, but it was submitted with a packet of screenshots on December 17, 2024. And some of the screenshots with dates appear to be duplicates. *Compare, e.g.*, Pltfs. App. 576 (FDA_001438), *with id.* at 578 (FDA_001440) *and id.* at 588 (FDA_001450); *compare also id.* at 577 (FDA_001439), *with id.* at 589 (FDA_001451). In fact, the entire range from FDA_001521-001584 (Pltfs. App. 659-722) appears to be duplicative of FDA_001430-001493 (Pltfs. App. 568-631).

Plaintiffs next claim that "many of the screenshots *do* provide information about the length of time that the product is out of stock." Pltfs.SJ.Mem.24. For support, Plaintiffs reference one screenshot from [redacted] that says "Date not provided by manufacturer" in a field for expected availability in a distribution center, Pltfs. App. 588 (FDA_001450), and another that says "[b]est dating available is 06/22/2025," *id.* at 589 (FDA_001451), which Plaintiffs read to suggest that Lilly's Mounjaro® 10mg product would not be available until June 2025.[8] Pltfs.SJ.Mem.24. These screenshots cannot do the work Plaintiffs need them to do. "Date not provided" is not an indication of how long a replenishment might take, much less that any delay will be long-term. And the record shows that Cardinal Health had all dosage strengths of Lilly's products in stock even though it restricted ordering Zepbound® 15mg to five units. Pltfs. App. 588 (FDA_001450). As for Plaintiffs' claims about the "best dating available" notice, their arguments are hard to take seriously given that they continually flip-flop on what they think that phrase means. In any event, the reading they prefer here makes no sense; it beggars belief to think that Lilly had [redacted] in net inventory as of [redacted], *see* Lilly. App. 230

[8] Plaintiffs appear to be caught in a bit of double-speak on this. At a different part of their summary judgment brief, Plaintiffs treat information about "dating" as relating to Lilly's products' expiration dates. *See* Pltfs.SJ.Mem.15 (quoting Pltfs. App. 589 (FDA_001451)). That Plaintiffs themselves are not entirely sure what their submissions are intended to show proves FDA's point.

(FDA_000575), but would not be able to get supply to a wholesaler or retail pharmacy until June of 2025. No wonder FDA did not put much stock in these screenshots.[9]

2. Plaintiffs next contend that FDA unfairly discounted survey reports which they claim show that tens of thousands of individuals were unable to obtain tirzepatide products at certain points in certain places. Pltfs.SJ.Mem.24-25. Plaintiffs say FDA's principal basis for rejecting these "reports" was the "information submitted by Lilly." *Id.* (quoting Lilly App. 28 (FDA_000028)). That is false—as the full quotation, which Plaintiffs misleadingly chop apart, plainly shows. In reality, FDA spent several pages explaining *why* it "conclude[d] that [these reports] do[] not undermine or outweigh the information submitted by Lilly." Lilly App. 28-31 (FDA_000028-000031).

As FDA went on to detail, these survey reports suffered from significant "limitations." *Id.* at 30 (FDA_000030). Looking at the Hims & Hers Health tracker, for example, FDA noted that this survey is just "an internet form that anyone can complete," and that it lacked significant controls, such as asking respondents to report only recent access challenges or instructing respondents to explain the nature of their trouble accessing the product. *Id.* at 29 (FDA_000029); *see also* Lilly.SJ.Mem.35 (discussing survey's frequently-asked-questions page broadly inviting "[a]nyone who has had trouble getting access to a GLP-1 medication in the past" to fill out the tracker (quoting FDA_001506 (Pltfs. App. 644)); *id.* (highlighting Lilly App. 218-20 (FDA_000563-65) depicting screenshots submitted on behalf of Lilly showing a response to Hims tracker using fake email). FDA also pointed to a report from Plaintiff OFA that purported to show

[9] Plaintiffs also cite FDA_001438-001440 (Pltfs. App. 576-78), FDA_001485 (Pltfs. App. 623), plus FDA_001529-001531, 001541-001542, 001544, and 001576 (Pltfs. App. 667-69, 679-80, 682, 714). As explained, it is not clear that FDA_001438, 001440, and 001450 (Pltfs. App, 576, 578, 588) are not duplicates of the same screenshot. So too for FDA_001439 and 001451 (Pltfs. App. 577, 589). And FDA_001485 (Pltfs. App. 623) could be a combination of FDA_001450 and 001451 (Pltfs. App. 588-89). Furthermore, the cites to the FDA_0015xx are simply part of the 63-page duplicate packet submitted to FDA and, therefore, have no additional probative value.

approximately 100 entries with a date and time (but no indication of what those dates and times signify), a patient zip code, and a yes/no answer to the question, "Have you attempted to have a prescription filled at more than one pharmacy?" Lilly App. 29 (FDA_000029) (referencing FDA_000708-000709 (Pltfs. App. 249-50)). As with the Hims & Hers tracker, FDA noted that this "report" did not include details of reporting individuals' experiences; nor was it clear how the information was collected. *Id.* at 29-30 (FDA_000029-000030). Indeed, it is not apparent that all the entries are trustworthy given that one entry is for the zip code 00000, which is not a valid U.S. zip code. *See* Pltfs. App. 249 (FDA_000708).

As FDA explained, these limitations were significant because they made it impossible to discern whether a patient's reported challenge involved a manufacturer supply issue, an inability to obtain a prescription from a doctor, or an insurance-coverage problem, undermining their probative value as to the statutory question. Lilly App. 30 (FDA_000030). Indeed, the submissions' opacity about what time period(s) they cover makes them unhelpful even as a cross-check; some (or all) of them may cover earlier periods during which all agree that (now-resolved) supply constraints existed. Furthermore, because there was no control on who could fill out the Hims & Hers form, it is possible that some individuals completed it numerous times. *Id.* Finally, even if some individuals were still encountering challenges in obtaining the medicines, that is not at odds with the conclusion that Lilly's supply was meeting demand, because those challenges can be readily explained by dynamics such as "ordering practices and incentives, cold chain logistical considerations, and retailer capacity constraints," *id.*, which have nothing to do with Lilly's supply.

Against this sensible reasoning, Plaintiffs contend that FDA's concerns about their evidence were "overblown." Pltfs.SJ.Mem.25. Skipping over FDA's analysis of the Hims & Hers tracker's shortcomings altogether, Plaintiffs say FDA should have given more credence to OFA's

time-stamped report because "inability to get a prescription filled at *two* pharmacies is as detailed as descriptions get on this scale," and the vast diversity of zip codes indicates that this is a nationwide issue. *Id.* But Plaintiffs do not even attempt to explain why they could not have asked for the reason the patient could not get a product at two pharmacies (i.e., was it manufacturer supply issue, the pharmacy's stocking decision, etc.). And as FDA pointed out, there is no indication of how this information was collected, Lilly App. 29-30 (FDA_000029-000030), or when the patient encountered a challenge. It was therefore eminently reasonable for FDA to give this evidence little, if any, weight.

3. Plaintiffs next accuse FDA of ignoring the various forms of "news" that were submitted. Pltfs.SJ.Mem.25-26. But FDA plainly did not "ignore[]" the various news articles Plaintiffs and their allies submitted; FDA explicitly acknowledged them in its decision memorandum, noting that it "reviewed various articles and blog posts submitted by various groups, as well as other news coverage." Lilly App. 33 (FDA_000033). FDA simply found that they did not "contain probative evidence relevant to the analysis FDA must conduct to determine whether a shortage has resolved." *Id.*

It is not hard to understand why. Take Plaintiffs' first example, an announcement dated December 10, 2024, stating that a national retail pharmacy "is no longer taking new GLP-1 patients" because of "market demand." Pltfs.SJ.Mem.25 (quoting FDA_000926 (Pltfs. App. 467)). As is clear from Plaintiffs' own description, this announcement addresses "GLP-1 patients" generally, not just patients in the market for Lilly's tirzepatide products—and it is undisputed that *other* GLP-1 medications *were* in shortage at the time. The announcement therefore has little to say about Lilly's ability to meet demand for its products.

Plaintiffs' other cited articles are similarly unhelpful:

- FDA_000738-000748 (Pltfs. App. 279-89) is an article (seemingly with some of the text cut off) in which Lilly's CEO discussed shortage specifically and compounding as a general matter. It says nothing about whether the shortage persists and contains no data or other information that contradicts any of Lilly's detailed submissions.

- Plaintiffs cite FDA_000965-000968 (Pltfs. App. 506-09) and FDA_001517 (Pltfs. App. 655) as articles "unfavorable to [FDA's] conclusions" that the agency supposedly ignored. But Plaintiffs fail to note that both articles are about Ozempic and Wegovy—neither of which Lilly manufactures or sells—and thus have no value in determining whether Mounjaro® and Zepbound® were in shortage.

- FDA_000802-000805 (Pltfs. App. 343-46) is an article relaying statements from Novo Nordisk's CEO, including this one: "We have a situation where there are far more patients who would like to have the treatment than what both Lilly and [Novo] can supply." Pltfs. App. 344 (FDA_000803). To state the obvious, FDA reasonably declined to give much weight to a statement from another company's CEO who discussed the matter in the aggregate and not as a statement about Lilly's ability to meet demand for its medicines (because he has little to no insight into Lilly's capabilities to meet demand for its products).

- FDA_000838 (Pltfs. App. 379) discusses the Hims & Hers tracker, which is unhelpful for all the reasons FDA explained, *see* Lilly App. 29-31 (FDA_000029-000031).

- FDA_000883-000900 (Pltfs. App. 424-41) covers President Biden's proposal to add coverage for weight-loss drugs to Medicare and Medicaid. That proposal was uncertain to go anywhere at the time, given that President Biden announced it after President Trump had already won the 2024 election. And it has not come to fruition. On the contrary, President Trump recently made clear that his Administration is not going forward with it at this time.[10]

- Finally, FDA_000945-000964 (Pltfs. App. 486-505) has a few paragraphs that describe two North Carolina pharmacists who were temporarily unable to obtain sufficient quantities of Lilly's products. But even taking this anecdotal evidence at face value, it cannot sustain the full weight of Plaintiffs' arguments. As Lilly has explained at length, temporary and isolated events are neither uncommon nor indicative of a shortage nationwide, which is what the statute requires.[11]

In short, FDA considered Plaintiffs' "news coverage" submissions. It just did not give them much weight, for the same reason that it declined to defer to Plaintiffs' other submissions: They suffer from severe evidentiary limitations when it comes to the factual question of whether

[10] *See* Alice Park, *Medicare Will Not Cover GLP-1 Drugs for Weight Loss*, TIME (Apr. 7, 2025), https://time.com/7275495/medicare-glp-1-drugs-weight-loss/.

[11] Plaintiffs also cite a submission detailing statements from the November 1, 2024, Cardinal Health earnings call. But that document does not appear to be part of the administrative record. *See* ECF No. 67, at 87.

the nationwide shortage of Lilly's medicines persisted. FDA's decisions regarding these articles' probative value were reasonable.

4. Finally, Plaintiffs accuse FDA of disregarding the sales volume of compounded tirzepatide in its consideration of demand. Pltfs.SJ.Mem.26 (citing Lilly App. 34 (FDA_000034)). But that tells only part of the story. To be sure, FDA explained why that evidence was of "minimal relevance" to assessing "current demand," as Plaintiffs' submissions failed to show that patients were using compounded tirzepatide products "*because* the approved products [we]re in shortage." Lilly App. 35 (FDA_000035). Additionally, and more importantly, FDA detailed why proper interpretation of the statute precludes it from considering *current* demand for a compounded copy of an approved medication—namely, because that would lead to the nonsensical result of an infinite loop of shortage declarations and resolutions. *See id.* at 34-35 n.103 (FDA_000034-000035).

But FDA went on to acknowledge that sales of compounded product are relevant to *projected* demand; it just found that Lilly could continue to meet demand even assuming that some or even all of that market *did* translate to demand for Lilly's products going forward. *See id.* at 36-40 (FDA_000036-40).[12] And there were good reasons to think much of the market for compounded tirzepatide would not translate to future demand for Lilly's FDA-approved products. Compounded products are often promoted for uses different from the indications FDA has approved, including by affiliated telehealth providers, so patients may be less likely to get a

[12] Indeed, the best evidence Plaintiffs put forward on this front was a news article claiming that compounding pharmacies may be "provisioning up to 2 million American patients with regular doses of semaglutide … or tirzepatide." Lilly App. 37 (FDA_000037). Setting aside the problem that the compounding market for *semaglutide* is not the compounding market for *tirzepatide*, *see id.*, 2 million is still considerably less than Lilly's excess inventory. *Cf. id.* at 38 (FDA_000038) ("[I]f we assume for purposes of this decision that the quantities reported by APC are accurate and add them to the quantities reported by OFA, the total amount remains small relative to Lilly's production and inventory.").

prescription from a physician for FDA-approved medicine. There also might not be insurance coverage for those off-label uses, and some compounded products use a different formulation than Lilly's products. *Id.* at 39 (FDA_000039); *see also id.* at 38 (FDA_000038). Once again, FDA's conclusion was eminently reasonable given the evidence before the agency, which did not provide "a sufficient, reliable basis to project the scope of this effect." *Id.* at 35 (FDA_000035).

* * *

At the end of the day, FDA's consideration of Lilly's thorough, quantitative submissions that presented both zoomed in and zoomed out pictures of supply and demand was reasonable, as was its conclusion that the record demonstrated that Lilly's supply was meeting or exceeding demand as of December 19, 2024, and would continue to do so. FDA's discounting of Plaintiffs' evidence was also reasonable, as that evidence either addressed the shortage issue only anecdotally, suffered from significant limitations that minimized its probative value, or both. The decision to declare the shortage of Mounjaro® and Zepbound® over was therefore amply supported by substantial evidence and neither arbitrary nor capricious.

III. Plaintiffs' "Contrary To Law" Claim Fails.

A. As Lilly explained in its summary judgment brief, FDA's interpretation of the FDCA reflects "the best reading of the statute." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024). The FDCA requires FDA to "maintain an up-to-date list of drugs that [it] determine[s] … to be in shortage in the United States." 21 U.S.C. §356e(a). Section 356e(a) does not define the term "shortage," but a neighboring provision does. *See id.* §356c(h)(2) (defining "shortage" or "drug shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug"). FDA has long understood §356e(a)'s use of the term "shortage" to carry that same meaning, *see* 21 C.F.R. §314.81(b)(3)(iii)(f) (adopting §356c(h)(2)'s definition for purposes of §356e(a)), and it applied that long-held understanding

here in determining that any shortage of Lilly's tirzepatide products was resolved as of December 19, 2024, if not earlier, *see* Lilly App. 2. That all makes sense. Courts typically presume "that the same term has the same meaning when it occurs here and there in a single statute," *Env't Def. v. Duke Energy Corp.*, 549 U.S. 561, 574 (2007); *see also Sorenson v. Sec'y of Treas.*, 475 U.S. 851, 860 (1986), and nothing in the relevant provisions remotely suggests that Congress intended "shortage" to mean something different in §356e(a), which focuses on the same supply-and-demand concepts as §356c(h)(2). Add it all up, and FDA's decision not only harmonizes §356e and §356c(h)(2) but is correct. *See* Lilly.SJ.Mem.38-43.

B. Plaintiffs' challenges to that conclusion range from bad to worse, and largely just try to dress up Plaintiffs' arbitrary-and-capricious arguments in statutory garb.

1. Plaintiffs first contend that, by conducting a "[redacted]" of supply and demand data, FDA violated the FDCA's requirement that the shortage list be "up-to-date," *see* 21 U.S.C. §356e(a). Pltfs.SJ.Mem.15. In Plaintiffs' mind, FDA needed to home in on a more truncated timeframe because "up-to-date" means "using or including the latest facts" or "keeping up with what is more recent in … information." Pltfs.SJ.Mem.15 (quoting Webster's New World College Dictionary 1571 (4th ed. 2007) (hereinafter "Webster's")). Plaintiffs are seriously confused both about what the statute requires and about what FDA did.

To be sure, the ultimate question is whether a drug is in shortage at the time of the decision. But that hardly means that present-day data is the only thing that matters, and the statute certainly contains no express language limiting it to only a narrow, recent time period. After all, while considering the latest information may be *necessary* for a decision to be up to date, the most recent round of data is not always *sufficient* to paint a full picture; sometimes, one can be truly up to date only by considering a more historical set of information. For example, to have an up-to-date

understanding of a batter's seasonal batting average, it is not enough to look at the box scores from the most recent homestand (let alone from just the most recent game). One certainly must take those latest facts into account; but one also must know what the batter's statistics have been over the rest of the season. Here, too, perhaps FDA would act contrary to law if it refused to consider "the latest facts" altogether when making a shortage/no-shortage determination. But FDA's decision to look to data from a broader period, covering both the recent past and projections about the near future, is both entirely sensible and entirely consonant with the statute's command, as that is the best way to ensure that in-the-moment figures are not masking something that stepping back a bit would reveal. Forcing FDA to operate with blinders on, as Plaintiffs' view of "up-to-date" would seemingly require, thus would risk inviting mistakes in both directions. In all events, it would not have made any difference here had FDA looked at some other, shorter "up-to-date" time period; all of the recent data supports (all of which FDA reviewed) supports its ultimate conclusion.

Judged against the sensible understanding, FDA properly assessed both whether Lilly is currently meeting and whether Lilly will continue to meet nationwide demand, and FDA properly concluded that it is and will. *See, e.g.*, Lilly App. 18 (FDA_000018) ("[T]hese reports support [FDA's] conclusion that supply *is meeting or exceeding* demand for these drugs[.]" (emphasis added)); *id.* at 27 (FDA_000027) ("[FDA] conclude[s] that based on our best judgment, supply *will meet or exceed* projected demand[.]" (emphasis added)). FDA considered recent past, present, and future data, including supply and demand across [redacted] stock reports from [redacted], and projected supply and demand data [redacted]. *See* Lilly.SJ.Mem.29-31. Only by looking at both a zoomed out and zoomed in supply and demand picture could FDA confidently conclude that Lilly had accumulated significant quantities of

surplus supply to keep up with demand fluctuations in the present and near future. In other words, the *historical* data supported FDA's conclusion that "supply is meeting or exceeding demand for [Lilly's] drugs" *in the present*. Lilly App. 20 (FDA_000020). That analysis aligns with the statute's dictate to "maintain an up-to-date list" of drugs in shortage in the United States. 21 U.S.C. §356e(a). Plaintiffs' myopic construction does not.

Plaintiffs complain that, under FDA's approach, Lilly's products might never again be in shortage because Lilly's cumulative supply now has such a lead over cumulative demand. Pltfs.SJ.Mem.15. But that very real possibility does not mean that FDA's approach is incorrect; it just reflects Lilly's efforts to increase its supply capacity to enable it to serve all demand for its products. Should there come a day when cumulative supply is outpaced by cumulative demand, a shortage would once again exist. But there was no shortage in December and there is no shortage now. Indeed, given Lilly's historic investment in manufacturing capacity, the data show Lilly's supply far outpacing the still-high demand. In any event, Plaintiffs' contrary argument underscores the problems with their position. Imagine a product for which demand is 100 units per day but current production maxes out at 99 units per day. In Plaintiffs' view, the product would be in shortage even if the manufacturer had a 1,000,000-unit surplus on hand and fulfilled every order. That "sounds absurd, because it is." *Sekhar v. United States*, 570 U.S. 729, 738 (2013).

2. Plaintiffs' next argument fares no better. Plaintiffs point out that §356c(h)(2) defines a "shortage" as "a period of time when the demand or projected demand for the drug *within* the United States" exceeds supply, and that §356e(a) similarly requires FDA to determine which drugs are "in shortage *in* the United States." From these italicized modifiers, Plaintiffs reason that FDA cannot make a nationwide determination and must instead find a shortage anytime supply exceeds demand in *any* part of the country, because "within" means "'inside the limits of,'"

Pltfs.SJ.Mem.16 (quoting Webster's 1571), not "coextensive with the limits of," *id.*, and "in" means "'contained or enclosed by,'" *id.* (quoting Webster's 719), not "exhaustive of," *id.* So, according to Plaintiffs, FDA violated the statute by "treating regional shortages as not cognizable." *Id.* at 15.

Once again, Plaintiffs are confused. While it is true that something can be "in" or "within" an area without being coextensive with or exhaustive of that area (e.g., a person in a room), it is also possible that something can be "in" or "within" a space in an exhaustive and coextensive manner (e.g., the air in a room). There is thus no reason to read the statutory prepositions to compel Plaintiffs' proposed interpretation. And there are a host of reasons why FDA was right not to do so—not the least of which being that Plaintiffs' non-coextensive interpretation would lead to rank absurdity, which is always to be avoided. *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982). After all, just as "New England, the Deep South, the Mountain West, and the Pacific Northwest are all 'within the United States' or 'in the United States,'" Pltfs.SJ.Mem.16, so too are individual states, cities, and towns—or even just individual pharmacies within any of those geographic units. Plaintiffs nowhere explain why their version of "in" and "within" would not require consideration of these more localized levels too. Nor could they, as their argument has no logical limiting principle. Under Plaintiffs' view, if one pharmacy in Fort Worth (which is obviously "in the United States") needs more of a drug on Monday than it bought on Friday, then there is a shortage, and the drug must go on the list, even if a new shipment is coming on Tuesday and even if every other pharmacy in Fort Worth (and the United States) is better at managing inventory and has an excess on hand. That is plainly not what Congress had in mind—not least of all because it would turn the shortage determination into a fool's errand.

Perhaps sensing the illogic of their position, Plaintiffs suggest that FDA's coextensive approach would allow manufacturers like Lilly to avoid shortages by declining to supply one or a few regions so its supply in other regions could exceed demand. *Id.* That makes no sense. Nor, under FDA's approach—i.e., the one the statute requires—could a manufacturer evade a shortage determination by supplying certain regions at the expense of others. If the demand in the unserved regions combined with the demand in served regions exceeded total supply, then a shortage would exist. Plaintiffs claim otherwise by yet again refusing to look at the full picture.

3. Plaintiffs next complain that FDA considered only Lilly's capacity to meet demand; in their view, had FDA considered "[d]elay[s] in shipping," it would have found a shortage. Pltfs.SJ.Mem.16 (quoting 21 U.S.C. §356e(b)(3)(F)). Lilly explained in its opening brief why this argument fails: Delays in shipping are relevant only if they cause a nationwide shortage, which certainly not every fleeting delay does. *See* Lilly.SJ.Mem.40-43. FDA adequately accounted for that dynamic by keeping its focus on supply and demand nationwide, not on isolated shipping delays that did not prove to have impacted the bigger picture in any meaningful way.

4. Finally, Plaintiffs once again fault FDA for purportedly considering demand for Lilly's FDA-approved products but not demand for compounded tirzepatide. Pltfs.SJ.Mem.17 (referencing Lilly App. 34-35 (FDA_000034-35)). According to Plaintiffs, FDA-approved drugs and non-tested, non-approved drugs must be treated as interchangeable because the FDCA treats compounded drugs as if they are "functionally the same drug." *Id.* Again, Plaintiffs are wrong.

For one thing, compounded tirzepatide products are not "functionally the same drug" as Lilly's FDA-approved medicines. Sections 503A and 503B of the FDCA exist because "some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA's new drug requirements." *Zyla Life Scis., L.L.C. v. Wells Pharma of Houston,*

L.L.C., 2025 WL 1076889, at *2 (5th Cir. Apr. 10, 2025). Congress mandated that compounders "must satisfy a host of additional statutory criteria" out of recognition that compounded drugs are *not* functionally the same as FDA-approved medicines. *Id.* While they may sometimes fill a patient-specific need, compounded products can be of inferior quality, not as effective, and far less safe—precisely because they have not been studied or approved by FDA.

Furthermore, as already explained, FDA *did* consider demand for compounded drugs; it just considered it as part of projected demand, rather than current demand. That makes eminent sense. As FDA has explained, *see* Lilly App. 34-35 n.103 (FDA_000034-35); FDA.SJ.Mem.7, if *demand* for compounded product had to be considered part of current demand, then *supply* of compounded product would also have to be considered. And that would produce a truly absurd statutory regime that Congress could not possibly have intended to craft, as it would leave shortages going on and off *ad infinitum*. First FDA would declare a shortage; then it would declare the shortage over as soon as the supply of FDA-approved *and compounded product* met demand for both; but then it would immediately declare *another* shortage, because the removal of the compounded supply (which could not lawfully continue once the shortage ended) would lead to another situation where demand exceeded supply; etc. etc. etc. *See* Lilly App. 34-35 n.103 (FDA_000034-35); FDA.SJ.Mem.7. Courts should avoid absurd interpretations, *Griffin*, 458 U.S. at 575, and FDA was right to do so as well.

What Plaintiffs really seem to be arguing is that FDA did not give enough weight to demand for compounded drugs. That is neither a statutory argument nor a fair characterization of the record. As already explained, FDA's treatment of demand for compounded tirzepatide was eminently reasonable, as there are legitimate and significant reasons to doubt that demand for compounded products will translate one to one to future demand for Lilly's products. *See supra*

pp.25-26; *see also* Lilly App. 38-39 (FDA_000038-39); (noting that different price points, different uses, and different formulations all make it questionable whether demand for compounded products will directly translate). But even if the entire market for compounded tirzepatide products did translate to projected demand for Lilly's products, FDA explained why Lilly's supply would still exceed demand, *id.* at 39, and Plaintiffs offer no basis to question that conclusion.

* * *

FDA properly interpreted and applied the relevant statutory provisions in determining that Lilly's products are not in shortage. Plaintiffs' view would lead to absurdity multiple times over. This Court should grant summary judgment to Defendants on Count Five.

CONCLUSION

The Court should deny Plaintiffs' motion for summary judgment as to all their claims.

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Respectfully submitted,

/s/ James R.P. Hileman

James R.P. Hileman

Dee J. Kelly, Jr.
State Bar No. 11217250
KELLY HART & HALLMAN, LLP
201 Main Street, Suite 2500
Fort Worth, TX 76102
Telephone: (817) 332-2500
Facsimile: (817) 878-9280
dee.kelly@kellyhart.com

Paul D. Clement (*pro hac vice*)
Erin E. Murphy (*pro hac vice*)
Matthew Rowen (*pro hac vice*)
CLEMENT & MURPHY, PLLC
706 Duke Street,
Alexandria, VA 22314
Telephone: (202) 742-8900
paul.clement@clementmurphy.com
erin.murphy@clementmurphy.com
matthew.rowen@clementmurphy.com

James F. Hurst, P.C. (*pro hac vice*)
Diana M. Watral, P.C. (*pro hac vice*)
Ryan Moorman, P.C. (*pro hac vice*)
James R.P. Hileman (*pro hac vice*)
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, Illinois 60654
Telephone: (312) 862-2000
Facsimile: (312) 862-2200
james.hurst@kirkland.com
diana.watral@kirkland.com
ryan.moorman@kirkland.com
james.hileman@kirkland.com

Jay P. Lefkowitz, P.C. (*pro hac vice*)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
Telephone: (212) 446-4800
lefkowitz@kirkland.com

Attorneys for Intervenor-Defendant
ELI LILLY AND COMPANY

CERTIFICATE OF SERVICE

I certify that on April 16, 2025, I served the foregoing document electronically in accordance with the Federal Rules of Civil Procedure.

/s/ James R.P. Hileman
James R.P. Hileman